

Public Health Service, HHS

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guardian of each dependent(s) must submit such documentation;

(4) Documentation showing the deceased smallpox vaccine recipient or vaccinia contact's gross employment income at the time the covered injury was sustained (e.g., the decedent's most recent Federal tax return or a pay stub from the time of the covered injury); and

(5) A description of all third-party payors that have paid for or that may be required to pay for the benefits described in §102.82(d)(3)(A). This description must include the amount of such benefits that have been paid or that may be authorized to be paid in the future. If the representative knows of no such third-party payor, he or she must certify to that fact. If, at any time, the representative becomes aware that a third-party payor may have such an obligation, he or she must inform the Secretary within 10 business days of becoming aware of this information.

§ 102.63 Documentation a representative filing on behalf of an eligible requester who is a minor or a legally incompetent adult must submit.

Before benefits will be paid under by the Program to an eligible requester who is a minor or legally incompetent adult, his or her representative must submit, in addition to the documentation submitted under subpart F and under §§102.60-102.62, the following:

(a) Documentation showing that the requester is:

- (1) A minor (e.g., birth certificate); or
- (2) A legally incompetent adult (e.g., court decree of incompetency); and

(b) Documentation showing that:

(1) In the case of a minor, the requester is the legal guardian of the minor (e.g., birth certificates for parents who are legal guardians or, for other legal guardians, a decree by a court of competent jurisdiction establishing the legal guardianship of a person other than the minor's parents under applicable State law). If a minor has more than one legal guardian, this information is required only of one legal guardian; or

(2) In the case of a legally incompetent adult, a decree by a court of competent jurisdiction establishing a guardianship or conservatorship of the

requester's estate under applicable State law.

Subpart H—Secretarial Determinations

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

§ 102.70 Determinations the Secretary must make before benefits can be paid.

(a) Before reviewing a Request Package, the Secretary will assign a Program number to the Request Package and so inform the requester (or his or her representative) in writing. All correspondence to the requester (or his or her representative) about a specific Request Package will be referenced by this Program number.

(b) Before the Secretary will pay benefits under this Program, he must determine that:

(1) The requester or his or her representative submitted a completed (to the fullest extent possible) and signed Request Form within the governing filing deadline;

(2) The requester meets the eligibility requirements set out in this part (including a determination that a covered injury was sustained); and

(3) The requester is entitled to receive benefits from the Program. In making this determination, the Secretary will decide the type(s) and amounts of benefits that will be paid to the requester.

(c) Once the Secretary has sufficient documentation to make an eligibility or benefits determination, he will make the decision in a timely manner.

§ 102.71 Insufficient documentation for eligibility and benefits determinations.

In the event that there is insufficient documentation in the Request Package for the Secretary to make the applicable determinations under this part, the Secretary will notify the requester, or his or her representative. The requester will be given 60 calendar days from the date of the Secretary's notification to submit the required documentation. If the requester is unable to provide the additional documentation, he or she may write to the Secretary

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and explain the reason that the requested documentation is unavailable and the efforts the requester has taken to obtain the documents. The Secretary may accept such a letter in place of the required documentation or disapprove the request due to insufficient documentation. If no documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the request. The Secretary also may require an authorization from the requester (or his or her representative) to try to obtain required documentation on his or her behalf.

§ 102.72 Sufficient documentation for eligibility and benefits determinations.

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to conduct an evaluation of a requester's eligibility, he will begin the review to determine whether the requester is eligible. If the Secretary determines that the requester is not eligible, the Secretary will inform the requester (or his or her representative) in writing of the disapproval and the options available to the requester, including reconsideration.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, he will, after receiving documentation from the requester for a benefits determination, either calculate the amount and types of benefits, as described in subpart I of this part, or request additional documentation in order to calculate the benefits that can be paid (e.g., an Explanation of Benefits from the requester's insurance company if none was provided).

(c) *Additional documentation required.* At any time after a Request Form has been filed, the Secretary may direct a requester to supplement or amend the Request Package by providing additional information or documentation.

§ 102.73 Approval of benefits.

When the Secretary has determined that benefits will be paid to a requester and has calculated the type and amount of such benefits, he will notify the requester (or his or her representative) in writing. The Secretary will

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make payments in accordance with § 102.83.

§ 102.74 Disapproval of benefits.

(a) If the Secretary determines that a requester is not eligible for payments under the Program, the Secretary will disapprove the request and provide the requester, or his or her representative, with a written notice of the basis for the disapproval and the options available to the requester, including reconsideration.

(b) The Secretary may disapprove a request at any time, even before the requester has submitted required documentation (e.g., the Secretary may determine that a requester did not meet the filing deadline, even before required documentation is submitted or reviewed).

Subpart I—Calculation and Payment of Benefits

SOURCE: 68 FR 70096, Dec. 16, 2003, unless otherwise noted.

§ 102.80 Calculation of medical benefits.

In calculating medical benefits, the Secretary will take into consideration all reasonable costs for those medical items and services that are reasonable and necessary to diagnose or treat a smallpox vaccine recipient or vaccinia contact's covered injury or its health complications, as described in § 102.31. The Secretary will consider and may rely upon benefits documentation submitted by the requester (e.g., bills, Explanation of Benefits, and cost-related documentation to support the expenses relating to the covered injury or its health complications), as required by § 102.60. The Secretary will make such payments only to the extent that such costs were not, and will not be, paid by any third-party payor and only if no third-party payor had or has an obligation to provide such services or items to the requester, except as provided in § 103.83(c) and § 103.84. There are no caps on medical benefits that may be provided under the Program.